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| 10/578,193 | 05/04/2006 | Karin Cabrera | MERCK-3160 | 8428 |
| 23599 | 7590 | 04/13/2009 | EXAMINER | |
| MILLENN, WHITE, ZELANO & BRANIGAN, P.C. | | | KENNEDY, TIMOTHY J | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/578,193 | Applicant(s) CABRERA ET AL. |
| | Examiner TIMOTHY KENNEDY | Art Unit 1791 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 April 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
6) Other: _____

DETAILED ACTION

1. The finality of the previous Office Action has been withdrawn.

Response to Arguments

2. Applicant's arguments, filed 4/6/2009, with respect to the rejection(s) of claim(s) 1-8 under U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art.

3. Regarding the rejection of claims 1-5, 7, and 8 using Ishizuka, in view of Eguchi and Tanaka. The reason that the arguments have been found persuasive is that after careful consideration the Examiner agrees that the motivation to combine the references is circumstantial, and neither Eguchi nor Tanaka provide one having ordinary skill motivation that one would be able to successfully produce a chromatography column produced by the method of the instant application using Ishizuka, in view of Eguchi and Tanaka.

4. Even though the arguments have been shown to be persuasive, the Examiner would like to point out some features (that did not play a role in the decision to withdraw finality) of the arguments are not recited in the rejected claims: the amount of shrinkage that would or would not occur by using the method of the instant application and whether or not the molding is removed from the capillary. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Regarding the rejection of claim 6 using Ishizuka, Eguchi, and Tanaka in further view of Zhang the Examiner still believes that the use of the Zhang reference is proper and that indeed Zhang teaches that a use of an organoalkoxysilane (i.e. methyltriethoxysilane) would exhibit low shrinkage compared to the commonly used tetramethoxysilane (TMOS) due to the fact that methyltriethoxysilane creates a more flexible and stronger sol. But for the clarification of this Office Action a new reference will be used for the rejection of claim 6.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The phrase "shrinkage rate" should be percent shrinkage, since the specification does not describe the "shrinkage rate" in terms of a normal rate unit (i.e. distance/time), but in terms of percentage. For examination purposes the phrase "shrinkage rate" will be interpreted as "percent shrinkage."

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lubda et al (U.S. PGPub 2003/0155676, already of record, herein after referred to as Lubda), in view of Karger et al (U.S. Patent 4,865,707, already of record, herein after referred to as Karger). Lubda teaches:

13. Provision of a gelling mold (paragraph 0013)
14. Filling of the gelling mold with monomer sol (paragraphs 0014 and 0027-0032)

15. Polymerization of the monomer sol and ageing of the resultant gel for the formation of pores, whereby the monolithic porous molding produced has an internal diameter of 0.5-50 mm (paragraphs 0015-0018 and 0021 (1 mm to 100 mm))
16. Lubda does not teach:
17. Activation of the gelling mold by surface etching, increasing the surface area and/or chemical modification
18. In the same field of endeavor Karger teaches etching (column 7, lines 40-59: etching would inherently increase the surface area due to the nature of the reaction) and chemical modification of the mold wall (column 6, lines 6-46) for capillaries that have inner diameters between 10 and 2000 microns. Chemical modification of the mold wall is used to provide better bonding between the mold wall and the gel, due to the fact that the chemical used has end units which are capable of attaching themselves to the mold wall and gel.
19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the mold wall activation as taught by Karger, using the Lubda method, since doing so would provided better bonding properties between the gel and the mold wall.
20. Regarding claim 2, Labda further teaches:
21. The gelling mold is made from glass, glass-coated stainless steel, or fused silica (paragraph 0043)
22. Regarding claim 3, Karger further teaches:

23. Activation in b) is carried out by increasing the inside surface area of the gelling mold by treating the inside surface with alkoxy silanes and/or organo alkoxy silanes or slurries or particles. (column 6, lines 34-36: the surface area would inherently increase due to the silanes extending from the mold wall)
24. Regarding claim 4, Karger further teaches:
25. Activation in b) is carried out by chemical modification of the inside surface of the gelling mold by treating the surface with bifunctional reagents (column 6, lines 6-46)
26. Regarding claim 5, Labda further teaches:
27. A sol-gel process is used for the production of the monolithic porous moldings (paragraphs 0014-0016)
28. Regarding claim 7:
29. A monolithic porous molding which has been polymerized into a gelling mold, obtainable by the process of claim 1.
30. The process of Labda in view of Karger would produce such a monolithic porous molding.
31. Regarding claim 8:
32. A chromatographic separation of at least two substances, comprising subjecting a mixture of said at least two substances to a mold according to claim 7.
33. The monolithic porous molding taught by Labda and Karger would be able to separate at least two substances, since separation of fluids is an inherent capability of chromatography columns.

34. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Labda and Karger as applied to claim 1 above, and further in view of Bhandarkar et al (U.S. Patent 6,457,329, herein after referred to as Bhandarkar). Regarding claim 6, Labda and Karger do not teach:

35. A monomer sol which exhibits low [percent shrinkage] through the addition of particles, fibers, and/or use of organoalkoxysilanes is used in step c).

36. In the same field of endeavor Bhandarkar teaches adding fumed silica or silica particles to sol-gel to help reduce the percent shrinkage (column 4, lines 18-39).

37. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the particles to reduce shrinkage as taught by Bhandarkar, using the previous method of Labda and Karger. Since Labda teaches shrinkage is a known issue in the use of sol-gel (paragraph 0006), one having ordinary skill would be able to surmise the addition of particles would help reduce shrinkage in sol gel produced chromatography columns.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

39. U.S. Patent 6,410,631: particles to reduce shrinkage

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY KENNEDY whose telephone number is (571) 270-7068. The examiner can normally be reached on Monday to Friday 9:00am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tjk

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 1791